UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION

ELLEN MERRIMAN and ROGER MERRIMAN,

Plaintiffs,

vs.

JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; and JOHNSON & JOHNSON.

Defendants.

MDL No. 2973
Case No. 2:20-md-02973 (BRM)(ESK)

JUDGE BRIAN R. MARTINOTTI
JUDGE EDWARD S. KIEL

DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO 6

Civil Action No: _____

COMPLAINT

Plaintiffs, ELLEN MERRIMAN and ROGER MERRIMAN, (hereinafter "Mrs. Merriman" and "Mr. Merriman"), by and through undersigned counsel, hereby complains against Defendants, JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; and JOHNSON & JOHNSON, (hereinafter collectively referred to as "Defendants"), and alleges as follows:

A. NATURE OF THE CASE

1. Elmiron®[1] is a prescription drug indicated for the relief of the pain and/or discomfort associated with interstitial cystitis (IC)—an uncommon, but painful bladder condition.

2. Upon information and belief, Defendants manufacture, promote, and sell Elmiron.

3. Upon information and belief, Defendants were and continue to be involved in and/or responsible for the post-market testing, development, labeling,[2] marketing and/or distribution of Elmiron.

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[1] Elmiron is the brand name for pentosan polysulfate sodium or "PPS" and will be referred to throughout this First Amended Complaint simply as "Elmiron".

[2] In the context of a pharmaceutical sold in the United States, the term "label", according to Federal and FDA regulations, includes the product's package insert (and Medication Guide, if applicable), package labeling, and container label. It is this definition of "label" or "labeling" that is intended throughout this Complaint.

4. Upon information and belief, Defendants also had knowledge of the prior pre-market testing, development, labeling, marketing and/or sale of Elmiron that was conducted by other entities prior to 2002.

5. During the more than two decades that Elmiron was available in the United States, Defendants knew (or should have known) of a causal association and/or causal relationship between Elmiron use and an increased risk of developing serious vision-related injuries, like those suffered by Plaintiff, Ellen Merriman.

6. But, upon information and belief, rather than attempt to study this potential safety concern, to instruct physicians on how to safely administer Elmiron therapy to avoid this risk, or to change the Elmiron drug label to warn of the risk of serious, permanent vision-related injuries, instead, Defendants did nothing. Instead, Defendants affirmatively represented that Elmiron was a safe and effective treatment for interstitial cystitis.

7. Indeed, prior to June 2020, the U.S. label for Elmiron made no mention of risk to patients' eyes or vision.

8. As a direct and proximate result of Defendants' wrongful and tortious actions and inactions with respect to Elmiron, Plaintiff, Mrs. Merriman, has suffered and will continue to suffer serious, permanent vision-related injuries.

9. As a direct and proximate result of Defendants' wrongful and tortious actions and inactions with respect to Elmiron, Plaintiff, Roger Merriman, has suffered and will continue to suffer the loss of his wife's consortium.

10. Accordingly, Plaintiffs have brought the instant suit and claims,

demands judgment against Defendants, and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

B. PARTIES

PLAINTIFFS

11. Plaintiff, Ellen Merriman, is a resident of the state of Virginia and currently resides in Aldie, Virginia.

12. Plaintiff, Mrs. Merriman, consumed and regularly used Defendants' product, Elmiron (pentosyn polysulfate sodium). As a result of her use of Elmiron, she suffered and continues to suffer severe physical and emotional injuries, including but not limited to toxic maculopathy of the retina, macular degeneration, and retinal pigment epithelium (RPE) changes.

13. Plaintiff, Roger Merriman, is a resident of the state of Virginia and currently resides in Aldie, Virginia.

14. Plaintiff, Mr. Merriman, as a result of Mrs. Merriman's use of Elmiron and the injuries sustained thereafter, has suffered and will continue to suffer the loss of his wife's consortium.

DEFENDANTS

JANSSEN PHARMA

15. Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC., ("Janssen Pharma") is a New Jersey corporation with a

principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

16. Upon information and belief, Defendant Janssen Pharma made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, marketing, promotion, labeling and/or regulatory approval of Elmiron in the State of New Jersey.

17. Upon information and belief, as part of its business, Defendant Janssen Pharma engages in the design, testing, labeling, packaging, marketing, advertising, distributing and/or selling of pharmaceutical products, including Elmiron, in the State of New Jersey.

ORTHO PHARMA

18. Defendant ORTHO-MCNEIL PHARMACEUTICALS, INC. ("Ortho Pharma") is a corporation organized under Delaware law with its principal place of business in 1000 US Highway 202, Raritan, New Jersey 08869.

19. Upon information and belief, Defendant Ortho Pharma made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, marketing, promotion, labeling and/or regulatory approval of Elmiron in the State of New Jersey.

JANSSEN R&D

20. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, (hereinafter "Janssen R&D") is a limited liability company

under the laws of New Jersey, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

21. Upon information and belief, Defendant Janssen R&D made consequential decisions and/or took significant actions concerning *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or regulatory approval of Elmiron in the State of New Jersey.

22. Upon information and belief, Defendant Janssen R&D has transacted and conducted business within the State of New Jersey and has derived substantial revenue from goods and products disseminated and used in the State of New Jersey.

23. Upon information and belief, as part of its business, Defendant Janssen R&D is involved in the research, development, sales, and/or marketing of pharmaceutical products, including Elmiron, including in the State of New Jersey.

24. Upon information and belief, and at all relevant times Defendant, Janssen R&D, was in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Elmiron.

JOHNSON & JOHNSON

25. Defendant Johnson & Johnson (hereinafter "J&J") is a New Jersey corporation, which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

26. Upon information and belief, at all relevant times, Defendants Janssen Pharma, Ortho Pharma, and Janssen R&D have been wholly owned subsidiaries of Defendant J&J, with the profits of each inuring to Defendant J&J's benefit.

27. Upon information and belief, as part of its business, Defendant J&J, and its "family of companies," is involved in the research, development, sale, and/or marketing of pharmaceutical products, including Elmiron, in the State of New Jersey, including in Middlesex County.

28. Upon information and belief, Defendant J&J made consequential decisions and/or took significant actions concerning, *inter alia*, the design, marketing, promotion, labeling and/or regulatory approval of Elmiron in the State of New Jersey.

29. Upon information and belief, Defendant J&J's decisions and/or actions with respect to Elmiron impacted, *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or FDA-approval of Elmiron in the United States, including in New Jersey and in Middlesex County.

C. JURISDICTION AND VENUE

30. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiffs exceed $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than Virginia, where the Plaintiffs are citizens and California, where the Plaintiff, Mrs. Merriman, was prescribed Elmiron.

31. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

32. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), because many of the Defendants reside there, all Defendants transact and conduct business

in New Jersey, and a substantial part of the acts and omissions giving rise to this Complaint occurred in New Jersey.

D. RELVANT FACTUAL BACKGROUND

INTERSTITIAL CYSTITIS

33. Interstitial cystitis ("IC")—which is also sometimes referred to as "painful bladder syndrome"—is a chronic bladder condition in which individuals experience bladder pain, pelvic pain, urinary frequency, urinary urgency, and/or nocturia.

34. According to the U.S. Centers for Disease Control, IC may impact as many as 5.1 out of every 100,000 Americans and up to 12% of U.S. women may have early symptoms of IC.[3]

35. IC is known to affect more woman than men.[4]

36. The American Urological Association (AUA) established guidelines, separating treatment options into six (6) tiers of increasingly invasive therapies for the treatment of IC. The treatments listed range from minimally invasive interventions, like simple lifestyle changes, to increasingly more invasive interventions, like invasive diagnostic studies or surgery. AUA recommends second-line treatment of IC to incorporate multi-modal pain management approaches including manual therapy and oral therapy options such as pentosan polysulfate (Elmiron). Elmiron is not the best nor the only option for treating interstitial cystitis.

[3] *See* Centers for Disease Control website, "What is Interstitial Cystitis (IC)?", available online at: https://www.cdc.gov/ic/index.html.
[4] *Id.*

37. There is no known cause of interstitial cystitis.

38. There is no known cure for interstitial cystitis and the condition is permanent or chronic.

FDA APPROVAL OF ELMIRON

39. On approximately June 11, 1991, Baker Norton Pharmaceuticals, a division of Ivax Pharmaceuticals, ("Baker Norton") submitted a New Drug Application ("NDA") for pentosan polysulfate sodium (NDA: 020193) (hereinafter "original NDA").

40. Pentosane polysulfate sodium is a semi-synthetically produced heparin-like macromolecular carbohydrate derivative.

41. Pentosane polysulfate sodium is sold under the brand name Elmiron.

42. According to the FDA, "the documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."[5]

43. Upon information and belief, the FDA deemed the original NDA non-approvable in approximately 1993.

44. Upon information and belief, in response, Baker Norton submitted additional materials, in support of the application, for FDA review.

45. Again, in approximately 1994, upon information and belief, the FDA issued a second non-approvable letter.

[5] *See* FDA Website, "New Drug Application (NDA)", available online at: https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

46. Upon information and belief, Elmiron was granted an Orphan Drug designation in 1995.

47. Upon information and belief, Baker Norton, again, submitted additional materials, in support of the application, for FDA review.

48. On September 26, 1996, the U.S. Food and Drug Administration (FDA) approved Elmiron for relief of pain or discomfort associated with IC.

49. The proposed label, approved by the FDA, included a Package Insert—directed at physicians and other healthcare providers—as well as a Medication Guide—directed at patients.

50. Beginning in approximately 1996, when Elmiron was first approved by the FDA, neither its Package Insert, nor its Medication Guide contained any warnings or information regarding the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

51. In short, the Elmiron labeling contained no warnings related to the risk of serious vision-related injuries caused by continued Elmiron use.

HISTORY OF ELMIRON NDA AND OWNERSHIP

52. Upon information and belief, from approximately 1996, when the NDA was approved, until approximately 1997, Baker Norton owned the trademark for Elmiron.

53. Upon information and belief, in approximately 2005, Teva Branded Pharmaceutical Products R&D, Inc., Teva USA, and/or Teva Pharmaceuticals, Inc., purchased Ivax Pharmaceuticals.

54. Upon information and belief, as part of that transaction, Teva Branded Pharmaceutical Products R&D, Inc., Teva USA, and/or Teva Pharmaceuticals, Inc., purchased the assets and liabilities of Ivax Pharmaceuticals, including, but not limited to Baker Norton.

55. Upon information and belief, Elmiron is a Registered Trademark of Teva Branded Pharmaceutical Products R&D, Inc., Teva USA, and/or Teva Pharmaceuticals, Inc., under license to Defendant Janssen Pharma.

56. Alternatively, upon information and belief, Elmiron is a Registered Trademark of Janssen Pharma, Ortho Pharma, Janssen R&D, J&J, and/or ABC Corporation 1-20.

57. Upon information and belief, from approximately August 2002 until August 2004, Defendant Janssen R&D held the NDA for Elmiron.

58. Upon information and belief, from July 2004 until August 2008, Defendants Ortho Pharma held the NDA for Elmiron.

59. Upon information and belief, since August 2008, Janssen Pharma, had held the NDA for Elmiron and continues to manufacture, sell, and/or distribute Elmiron in the United States.

60. Alternatively, upon information and belief, since approximately 1997, Janssen Pharma, Ortho Pharma, Janssen R&D, J&J, and/or ABC Corporation 1-20 have held the NDA for Elmiron and continue to manufacture, sell, and/or distribute Elmiron in the United States.

61. There is no generic, non-bioequivalent form of Elmiron sold in the United States.

62. Upon information and belief, given the chronic and permanent nature of IC, Defendants anticipated (or reasonably should have anticipated), that patients taking Elmiron would likely do so indefinitely.

63. Upon information and belief, sales of Elmiron generate approximately $150M in annual revenue in the United States.

DEFENDANTS' INDIFFERENCE TO INCREASING SAFETY CONCERNS

64. From approximately 1997 to the present, Defendants have received multiple Adverse Event Reports ("AER") from medical professionals concerning Elmiron. These AERs included serious visual complication believed to be associated with Elmiron use, ranging from retinal haemorrhage to macular degeneration to, even, unilateral blindness.

65. Indeed, the reports of serious visual complications were not unique to the United States and, upon information and belief, serious visual complications were reported to Defendants and recorded in other AER databases around the world, where Elmiron was sold, like EudraVigilance—the European Medicines Agency's ("EMA") adverse event database.

66. It is widely recognized and accepted in the pharmaceutical industry that reported AERs represent only a small fraction of adverse events associated with and/or caused by a particular drug.

67. More recently, since approximately 2018, outside, independent studies and reports, documented in medical literature raise similar concerns regarding Elmiron's safety and propensity for causing serious visual complications including, but not limited to, pigmentary maculopathy.

68. In approximately May 2018, Emory Eye Center in Atlanta, Georgia, published a case study of six adult patients, who were treating their IC symptoms with Elmiron. The Emory physicians observed and documented significant pigmentary maculopathy in all six patients, who each had a long-history of Elmiron use.

69. In approximately April 2019, the Emory Eye Center published a further case study of ten patients. The doctors reported that over the last four years, patients who did not treat IC with pentosane polysulfide sodium were not experiencing pigmentary maculopathy.

70. The first clinical population-based study came from Kaiser Permanente in 2019. Kaiser Permanente conducted a study based of 4.3 million patients. Patients showed clear evidence of this specific maculopathy, which was believe was associated with Elmiron exposure.

71. The Kaiser Permanente research was presented at the "AAO 2019"—the annual meeting of the American Academy of Ophthalmology at Moscone Center, San Francisco. The study revealed that eye damage increased with the quantity of Elmiron intake.

72. A Harvard Medical School case study, published in 2019, examined a female with a history of eighteen years of Elmiron use at a low dose of 200mg/day. She initially presented with symptoms that included blurry vision, difficulty seeing at night, and pigmentary changes in the retina. Two years later, she returned for evaluation; her eye examination revealed more extensive eye damage, consistent with pigmentary maculopathy. The Harvard physicians concluded that long-term Elmiron use results in progression of pigmentary maculopathy, even if the drug is stopped.

73. A study published in April 2020 by the Canadian Ophthalmological Society concluded, *inter alia*, the prevalence of Elmiron-induced macular toxicity posed a "significant risk" to patients taking Elmiron.

DEFENDANTS' WARNED ABROAD, BUT NOT IN THE UNITED STATES

74. Upon information and belief, beginning in approximately 2019, Defendants took steps to warn consumers and physicians in other countries of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron.

75. For instance, in approximately September of 2019, Defendants revised the Elmiron label in Canada to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron, as follows:

> **Ophthalmologic**
>
> Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosan polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptation. All patients should have regular ophthalmic examinations for early

> detection of pigmentary maculopathy, particularly those with long term use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.

76. Likewise, in approximately 2019, Defendants "agreed" with an EMA Committee's recommendation that Elmiron's label be changed to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with long-term use of Elmiron.

77. The Elmiron label in EMA countries now warns:

> All patients should have an ophthalmologic examination after 6 months of use of PPS for early detection of pigmentary maculopathy, and, if there are no pathologic findings, regularly after 5 years of use (or earlier, in case of visual complaints). However, in case of relevant ophthalmologic findings, a yearly examination should be conducted. In such situations, treatment cessation should be considered.

78. The Elmiron label used in EMA countries further admits that "eye disorders", like pigmentary maculopathy, are "uncommon" undesirable effects of the medication.

79. In approving these changes to the Elmiron label, the EMA Committee for Medicinal Products for Human Use (CHMP) created a report, which, upon information and belief, Defendants received. As relevant, here, the CHMP in its report noted that such a warning regarding ophthalmological side effects of Elmiron was needed, in part, because pigmentary maculopathy "might not be easily recognized by the urology community".

DEFENDANTS HAD A DUTY TO PROTECT U.S. CONSUMERS, BUT DID NOT

80. At all relevant times, Defendants had a duty to craft an adequate label with respect to Elmiron.

81. At all relevant times, Defendants had a duty to ensure that the warnings in the Elmiron label were adequate, at all times, for as long as the drug remained available for sale in the United States.

82. At all relevant times, Defendants had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Elmiron, after the Elmiron NDA was approved, for as long as the drug remained available for sale in the United States.

83. At all relevant times, Defendants had a duty to revise the Elmiron label to include a warning regarding the risk of serious vision-related injuries as soon as there was reasonable evidence of a causal association between vision-related injuries and Elmiron use.

84. Upon information and belief, by approximately 2001, Defendants had reasonable evidence of a causal association between serious vision-related injuries and Elmiron use.

85. Upon information and belief, by approximately 2001, a reasonable pharmaceutical company would have understood the existence of a causal association between serious vision-related injuries and Elmiron use.

86. Upon information and belief, by approximately 2001, Defendants learned Elmiron use could cause serious vision-related injuries.

87. Upon information and belief, by approximately 2001, a reasonable pharmaceutical company would have understood the existence of a causal association between serious vision-related injuries and Elmiron use.

88. Upon information and belief, despite reasonable evidence of causal association, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, Mrs. Merriman, developing serious vision-related injuries as a result of taking Elmiron.

89. Upon information and belief, despite understanding Elmiron could cause vision-related injuries, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

90. Accordingly, pursuant N.J.S. §2A:58C-5(c), Defendants are liable to Plaintiffs for punitive damages.

HOW DEFENDANTS' MISCONDUCT ENDANGERED U.S. CONSUMERS

91. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron, they would have discovered prior to seeking FDA approval, that long-term Elmiron use can cause serious visual injuries, including, but

not limited to, pigmentary maculopathy.

92. Upon information and belief, despite understanding patients taking Elmiron would likely remain on the medication for long periods of time, Defendants failed to test and study the long-term safety and efficacy of the drug, prior to seeking FDA approval.

93. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron's long-term effects, they would have discovered prior to seeking FDA approval, that long-term Elmiron use can cause serious visual injuries, including, but not limited to, pigmentary maculopathy.

94. Upon information and belief, despite post-approval adverse event reports and other clinical evidence, Defendants failed to continue to test and study the safety and efficacy of Elmiron, particularly in patients who used the drug for long periods of time.

95. Upon information and belief, from the date all Defendants received FDA-approval to market Elmiron in the United States, Defendants each of them made, distributed, marketed, and sold Elmiron without adequate warning to Plaintiff, Mrs. Merriman, or Plaintiff's prescribing physicians that Elmiron was associated with and/or could cause retina damage in patients who used it, and that all Defendants had not adequately conducted complete and proper testing and studies of Elmiron with regard to retina damage.

96. Upon information and belief, Elmiron concealed and/or failed to completely disclose their knowledge that Elmiron was associated with and/or could

cause retina damage as well as their knowledge that they had failed to fully test or study said risk.

97. Upon information and belief, all Defendants ignored the association between the use of Elmiron and the risk of developing permanent and disfiguring visual complications, including, but not limited to, pigmentary maculopathy and retina damage.

98. Upon information and belief, all Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of retina damage of Elmiron, but similar efficacy compared to less potent products.

99. Upon information and belief, all Defendants failed to provide adequate instructions to U.S. healthcare professionals and patients regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

100. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

101. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, that the risk of potentially serious visual complications increases the longer a patient continues to use Elmiron.

102. Upon information and belief, all Defendants failed to warn and/or to

provide adequate instructions to U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop taking Elmiron in the event that potentially serious visual complications developed while using Elmiron.

103. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, of the true risk of retina damage to patients taking Elmiron as to compared to other similarly efficacious pharmaceutical products.

104. All of Defendants' failures to provide adequate instructions and/or disclose information—which Defendants each possessed regarding the failure to adequately test and study Elmiron for the risk of serious visual complications—further, rendered the Elmiron Package Insert, Medication Guide, and other educational and/or promotional materials inadequate.

105. Despite AERs from healthcare professionals and consumers around the world, from approximately 1997 until approximately September 2019, Elmiron never warned—in any country or market—of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

ELMIRON U.S. LABEL CHANGE

106. From when Elmiron was first sold in the United States until June 16, 2020, Defendants' U.S. Elmiron did not warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

107. Indeed, from when Elmiron was first sold in the United States until June 16, 2020, upon information and belief, Defendants made no attempt to warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

108. Upon information and belief, beginning on June 16, 2020, Defendants' Elmiron label contained the following language as to the risk of serious, vision-related complications:

> **WARNINGS**
>
> **Retinal Pigmentary Changes**
> Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor.
>
> Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations

should be continued given that retinal and vision changes may progress even after cessation of treatment.

109. Upon information and belief, Defendants have never made, at any time, efforts to warn healthcare providers directly using a "Dear Doctor" or "Dear Healthcare Provider" letter to inform healthcare providers of the changes in the Elmiron label or of the risk of serious, vision-related complications caused by continued Elmiron use.

110. By contrast, in Canada on December 15, 2020, Defendants issued a letter to "[h]ealthcare professionals including urologists, urogynecologists, ophthalmologists, optometrists, family physicians, and pharmacists," warning that Elmiron can cause serious vision-related injuries, including pigmentary maculopathy and noting that these injuries may be "irreversible" and that "changes [in vision] may progress even after cessation of [Elmiron] therapy."

111. The December 15 letter was signed by the Vice President, Regulatory, Quality, Risk Management and Drug Safety for Janssen, Inc., which is a subsidiary of Defendant J&J.

E. PLAINTIFF'S USE OF ELMIRON

112. Upon information and belief, at the direction of her physician, Plaintiff, Ellen Merriman, began taking Elmiron continuously and daily from approximately 2000 to 2018 for the treatment of her IC-related pain.

113. In approximately 2018, Plaintiff was diagnosed with vision-related injuries, including, but not limited to, toxic maculopathy of the retina.

114. It was within two years of the date of the filing of this Complaint that

Plaintiff first knew, or had any reason to know, that her vision-related injuries, including, but not limited to, toxic maculopathy of the retina created a cause of action against the manufactures of Elmiron.

115. As a direct result of her consistent, long-term exposure to Elmiron, Plaintiff suffered serious vision-related injuries, including, but not limited to, toxic maculopathy of the retina, macular degeneration, and retinal pigment epithelium (RPE) changes.

116. Because of Defendants' actions and inactions with respect to Elmiron, Plaintiff has suffered and will continue to suffer serious vision-related injuries, as well as other personal injuries, physical pain and mental anguish, including diminished enjoyment of life, and other economic losses, including past and future medical expenses.

117. By reason of the forgoing acts and omissions, Plaintiff has suffered damages and harm, including, but not limited to, emotional distress, medical expenses, other economic harm.

118. Plaintiff accordingly seeks damages associated with these injuries.

119. Plaintiff would not have used Elmiron had any or all of Defendants' properly disclosed the risks associated with its use.

120. Plaintiff's injuries could have been avoided or would have been less severe if Defendants had properly disclosed the risks associated with Elmiron use.

121. Despite diligent investigation by Plaintiff into the cause of these injuries, including consultations with medical providers, the nature of Plaintiff's

injuries and damages and their relationship to Elmiron was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

122. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold information from the Plaintiff, Mrs. Merriman, her healthcare providers, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

123. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold safety-related warnings from the Plaintiff, her family members, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

124. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold instructions from the Plaintiff, her family members, and the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

125. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the long-term safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

126. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that Elmiron was safe for its intended use. Defendants disseminated

labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers, and the general public regarding the safety of Elmiron knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with long-term Elmiron use. They did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Elmiron's safety.

127. Further, Defendant actively concealed the true risks associated with the use of Elmiron, particularly as they relate to the risk of serious vision-related injuries, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, her healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warnings required to safely prescribe and take Elmiron and no vision-related adverse side effects associated with use of Elmiron.

128. Due to the absence of any warning by the Defendants as to the significant health and safety risks posed by Elmiron, Plaintiff was unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to Plaintiff, her healthcare providers, or the general public.

129. Due to the absence of any instructions for how to identify and/or monitor Elmiron patients for potential vision-related complications, Plaintiff were unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to Plaintiff, her healthcare providers, or the general public.

130. Given Defendants' conduct and deliberate actions designed to deceive

Plaintiff, her healthcare providers, and the general public with respect to the safety and efficacy of Elmiron, Defendants are estopped from relying on any statute of limitations defenses.

COUNT I: STRICT LIABILITY — DEFECTIVE DESIGN AND INADEQUATE TESTING

131. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

132. At all times relevant herein, Defendants placed Elmiron into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products were safe and/or efficacious for their intended purpose. Insofar as Elmiron could not be used safely without the unreasonable risk of harm, it was ineffective for the purpose for its intended use, *i.e.*, the treatment of IC-related pain.

133. Defendants were the designers, manufacturers and/or suppliers of Elmiron and are strictly liable to Plaintiffs for designing, manufacturing, distributing, marketing, selling and placing it into the stream of commerce.

134. The Elmiron manufactured, designed, marketed and/or supplied by Defendants was defective in design, manufacture or formulation, in that, when it left Defendants' control, the harm of said products outweighed any benefit derived therefrom, which rendered it inherently dangerous and/or defective, thereby causing serious harm to Plaintiffs.

135. The Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the control of

the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

136. The Elmiron designed, marketed, manufactured and/or supplied by Defendants were defective due to inadequate pre-market and post-market testing.

137. At all times relevant hereto, Defendants encouraged the use of Elmiron as a superior form of treatment for IC, despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of Defendants' widespread promotional activity, physicians began commonly prescribing Elmiron as a safe and effective treatment for IC-related pain.

138. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events associated with a particular drug.

139. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events caused by a particular drug.

140. A reasonable pharmaceutical company would continue to study a drug—even after it was commercially available for sale—to distinguish between undesirable effects caused by the drug and undesirable effects associated with the drug.

141. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff, Mrs. Merriman, suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff has suffered and will continue to suffer economic

losses, loss of normal life, and physical and mental pain and suffering.

142. Alternatively, the Elmiron designed, marketed, manufactured and/or supplied by Defendants were defective in design, for the intended patient population, due to the low bioavailability of the drug.

143. Alternatively, Elmiron that was manufactured, marketed, supplied and/or sold by Defendants and prescribed to and used by Plaintiff was defective in design, manufacture or formulation in that when it left the hands of the manufacturer and/or supplier/seller, it was unreasonably dangerous, and was more dangerous that an ordinary consumer would expect and more dangerous than other methods of treatment for IC-related pain.

144. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns, including adverse event reports—both in the United States and around the world, where Elmiron was sold—and to deliberately not study the long-term safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

145. Defendants improperly, negligently falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Elmiron to and/or from the FDA, that had the FDA known of such facts, the Product would have never been approved and no physician would have been able to prescribe Elmiron to Plaintiff.

146. Defendants improperly, negligently, falsely, and deceptively misrepresented and/or knowingly omitted, suppressed, and/or concealed facts of such

materiality regarding the safety and efficacy of Elmiron to and/or from the FDA, that had the FDA known of such facts, Elmiron would have never been approved with the warnings and instructions for use that accompanied Elmiron and/or were provided to prescribing physicians and the public, so that Elmiron would not have been prescribed to nor used by Plaintiff.

147. Because Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, no statutory presumptions in favor of Defendants are warranted.

COUNT II: STRICT LIABILITY — FAILURE TO WARN

148. Plaintiffs incorporate by reference each and every preceding paragraph as if fully set forth herein and further alleges as follows:

149. At all relevant times hereto, Defendants advertised and promoted the use of Elmiron as a safe method of treatment for IC despite the lack of adequate testing for either safety or efficacy and after it knew or reasonably should have known that Elmiron suffered from a design and/or manufacturing flaw.

150. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events associated with a particular drug.

151. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events caused by a particular drug.

152. A reasonable pharmaceutical company would have recognized an emerging safety signal relative to the risk of vision-related injuries and would have changed the Elmiron label to reflect, at a minimum, that Elmiron use was associated with serious, vision-related complications.

153. Despite the fact that evidence existed that the use of Elmiron was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Elmiron and in fact, acted to deceive the medical community and public at large, including all potential users of Elmiron by promoting it as a safe and effective method of chemotherapy, when, in fact, it was unsafe and alternative and safer methods for pharmacological treatment existed.

154. Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that Elmiron created, among other things, a significantly increased risk of permanent and disfiguring eye damage by consumers and Defendants failed to adequately warn of said risks and the severity of such adverse effects, resulting in harm to Plaintiffs, as set forth, herein.

155. Defendants failed to warn physicians and users of Elmiron of the aforementioned dangers and adverse side effects.

156. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff, Mrs. Merriman, suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will

require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff has suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

WHEREFORE, Plaintiffs respectfully prays of this Court and demands of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiffs under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT III: CONSUMER FRAUD.

157. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

158. Knowing the falsity and/ misleading nature of their claims, Defendants engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts relative to the safety and efficacy of Elmiron.

159. Defendants intended such actions to mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Elmiron.

160. Such actions did, in fact, mislead patients, healthcare providers, and the

general public with respect to the safety and efficacy of Elmiron.

161. Reliance of information, labeling, and/or statements made by Defendants with respect to the safety and efficacy of Elmiron, by patients, including Plaintiff, Mrs. Merriman, healthcare providers, and the general public, was reasonable.

162. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff has suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

163. Plaintiffs suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable commercial practices as set forth above, and seeks treble damages, attorney's fees and costs of suit.

WHEREFORE, Plaintiffs respectfully prays of this Court and demand of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiffs under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and

the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT IV: BREACH OF EXPRESS WARRANTY

164. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

165. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Elmiron in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals and consumers, including Plaintiff, Mrs. Merriman, or persons responsible for consumer.

166. Elmiron, materially failed to conform to those representations made by Defendants in Package Inserts, and otherwise, concerning the properties and effects of Elmiron respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and used with in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Elmiron sold to Plaintiff.

167. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered permanent and grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Elmiron, Plaintiff purchased and used Elmiron as prescribed and instructed by Plaintiff's physician, leading to Plaintiff's injuries.

WHEREFORE, Plaintiffs respectfully pray of this Court and demand of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiffs under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT V: LOSS OF CONSORTIUM

168. Plaintiff, Roger Merriman, incorporates by reference all preceding paragraphs as if fully set forth herein.

169. At all times relevant to this action, Mr. Merriman was the lawful husband of Plaintiff, Mrs. Merriman.

170. As a result of the injuries and harm sustained by Mrs. Merriman, as a result of the acts and omissions of Defendants described above, Mr. Merriman has suffered and will continue to suffer the loss of his wife's services, society and companionship

WHEREFORE, Plaintiffs respectfully pray of this Court and demands of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiffs under the law for his loss of consortium; (2) an award of attorneys' fees and costs; (3) prejudgment interest and the costs of suit; and (4) such other relief as this Court may

deem just and proper.

PLAINTIFFS ARE ENTITLED TO PUNITIVE DAMAGES

171. The acts and omissions of Defendants described above consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

172. Defendants' actions amounted to actual malice or reckless indifference to the likelihood of harm associated with their acts and omissions.

173. Defendants misled both the medical community and the public, including Plaintiff, Mrs. Merriman, and her physicians, by making false representations about the safety and effectiveness of Elmiron and by failing to provide adequate instructions and training concerning its use.

174. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Elmiron despite available information demonstrating that drug could interfere with the normal health, healing, proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells; cause potentially irreversible vision issues and retinal harm; cause PPS-toxicity and/or PPS-maculopathy; cause irreversible damage to vision, eyes, and retinas; and cause maculopathy.

175. Defendants were or should have been in possession of evidence demonstrating that Elmiron use could interfere with the normal health, healing,

proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells; cause potentially irreversible vision issues and retinal harm; cause PPS-toxicity and/or PPS-maculopathy; cause irreversible damage to vision, eyes, and retinas; and cause maculopathy. Nevertheless, Defendants continued to market Elmiron by providing false and misleading information with regard to its safety and effectiveness.

176. Defendants failed to provide warnings that would have dissuaded health care professionals from using Elmiron, thus preventing health care professionals, including Plaintiff's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Elmiron.

177. As a proximate result of Defendants' acts and omissions, Plaintiff suffers from retinal damage and other visual symptoms resulting from Plaintiff's ingestion of Elmiron.

178. As a result of Plaintiff's injuries, Plaintiffs have endured substantial pain and suffering, have incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

179. Plaintiffs have suffered and will continue to suffer economic loss, and have otherwise been emotionally and economically injured.

180. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

181. Plaintiffs' injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiffs seeks actual and punitive damages from the

Defendants.

182. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

183. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

ACCORDINGLY, Plaintiffs are entitled to recover punitive damages.

PRAYER FOR RELIEF

184. Plaintiffs respectfully request the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate Plaintiffs:

a. Medical Expenses;

b. Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort of Plaintiffs;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and post judgment interest;

g. Exemplary and Punitive Damages;

h. Treble damages;

i. Reasonable and necessary attorneys' fees, costs, pre-judgement interest; and

j. Such other relief to which Plaintiffs may be justly entitled.

WHEREFORE, the Plaintiffs demand judgment of and from Defendants in an amount for compensatory damages against all Defendants for pain and suffering actual damages; consequential damages; exemplary damages, jointly and severally against all Defendants; interest on damages (pre- and post-judgment) in accordance with the law; Plaintiffs' reasonable attorney's fees, as well as costs of court and all other costs incurred; and such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

The Plaintiffs hereby demand a trial by jury on all counts and as to all issues.

Dated: August 25, 2021

Respectfully submitted,

By: _____

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DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, HUNTER J. SHKOLNIK, is hereby designated as trial counsel in this matter.

Hunter J. Shkolnik

CERTIFICATION

Plaintiffs certify that the foregoing action is not the subject of any other action pending in any other court or arbitration proceeding and that no other action or arbitration proceeding is contemplated at this time. Plaintiffs further certify that no other persons are known to them who should be joined as parties at this time. Plaintiffs are aware that if the statements contained within this certification are knowingly false, that she may be subject to punishment.

Dated: August 25, 2021

Hunter J. Shkolnik